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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,223	11/19/2001	John E. Hogan	37-55	8201

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EXAMINER	
MICHENER, JENNIFER KOLB	
ART UNIT	**PAPER NUMBER**
1762	

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,223	HOGAN ET AL.	
	Examiner	Art Unit	
	Jennifer K Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/29/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-158* is/are pending in the application.

4a) Of the above claim(s) *61,62,72,88,89,99,117,118 and 128* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60,63-71,73-87,90-98,100-116,119-127 and 129-156* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/199/2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/966,582.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/19/01;2/28/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Examiner draws Applicant's attention to his response to restriction requirement of 1/29/04 in which he lists the claims which read on the elected species. Examiner believes that claims 74, 124, and 125 have been omitted from this list and she has examined them with the others, below. If Applicant disagrees or if Examiner has overlooked something, please so state.

Claim Objections

2. Claims 87 and 158 are objected to because of the following informalities: In claim 87, an independent claim, the preamble should read –A method—instead of "The method" and in claim 158, the word "does" should be replaced with –dose--. Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 60, 63, 78, 80, 81, 83-87, 90, 105, 107-108, 110-116, 119, 134, 136-137, and 139-142 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 26, 27, 41, 56, 57, 66, 71, 79, and 80 of U.S. Patent No. 6,117,479. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach electrostatic coating of tablets with powdered active agent.

The patent teaches application of a bioactive agent to a pharmaceutical substrate, which appear to contain different active ingredients. When using an electrostatic method of the patent, it would have been obvious to one of ordinary skill in the art to select triboelectric or corona discharge species of electrostatic coating from the broad genus group with the expectation of success. Bioactive agents are inclusive of the species required by the claims.

5. Claims 60, 63-71, 73-87, 90-98, 100-116, 119-127, and 129-158 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34, 39, 44, 49, 52, 57, 61-72, 75, 81-93, 98-100, 105, 114-115, 117, 122, 127-128, 131-135, 138, 141, 142, 145-148, 151-153, 161-172, 177-179, 185, 186, 196, 201, 206, 210-218, 221, 224-228, 231, 233, and 236-238 of U.S. Patent No. 6,406,738. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the patent claims contain the limitations of the application claims even though they may be combined in different manners.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 60, 78, 83, 87, 105, 110, 114, 115, 116, 134, and 139 are rejected under 35 U.S.C. 102(e) as being anticipated by Pletcher et al. (US 5,714,007).

Pletcher teaches electrostatically coating a pharmaceutical dosage core with an active material in a powder form (abstract). Pletcher teaches tribo-electric charging of the powder. The powder moves from a source to the dosage core by electric potential differences in electrostatic coating operations. The dosage core of Pletcher is a tablet or the like which is a "conventional" shape. Coating a tablet, etc. with an active agent or drug inherently produces a dosage as that is the unit used to deliver the drug.

8. Claims 60, 78, 83, 87, 105, 110, 111, 114, 115, 116, 134, and 139-140 are rejected under 35 U.S.C. 102(e) as being anticipated by Sun et al. (5,846,595).

Sun teaches electrostatically coating a pharmaceutical dosage core with an active drug in powder form (abstract; col. 2; col. 19). Sun teaches tribo-electric or corona discharge charging of the powder (col. 31, line 48; col. 33, line 37). The powder moves from a source to the dosage core by electric potential differences (col. 2), specifically Sun teaches that the substrate is held from above (abstract). The dosage core of Sun is a tablet or the like which is a "conventional" shape. Coating a tablet, etc. with an active agent or drug inherently produces a dosage as that is the unit used to deliver the drug.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 79, 82, 86, 106, 109, 113, 135, 138, 142, 153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pletcher or Sun.

Pletcher and Sun teach coating capsules, tablets, or vaginal and rectal suppositories and the like with medicaments (col. 3, line 67 of Pletcher and col. 19 of Sun). Pletcher and Sun fail to teach the specific types of medicaments used, however it is Examiner's position that it would have been obvious to one of ordinary skill in the art to have selected an appropriate drug for use in the methods of Pletcher or Sun based on the medical condition to be treated. Specifically it would have been obvious to coat the suppositories of Pletcher or Sun with laxatives, anti-fungals, or colorectal agents, as required by the claims, which are often administered in that form.

The powders of Pletcher and Sun appear to be electrets.

It would have been obvious to one of ordinary skill in the art to incorporate an agent that disintegrates into the powder to allow for disintegration in the stomach or intestine to allow entry of the drug into the blood stream.

13. Claims 64-71, 73-76, 91-98, 100-103, 120-127, 129-132, 143-147, 149-150, 154-155, and 157-158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun. Sun teaches powder pharmaceutical ingredients with sizes ranging from 4-8 microns (col. 31, line 56), overlapping the ranges claimed by Applicant.
Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Sun's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).
Sun teaches that the pharmaceutical powder ingredient may comprise more than one pharmaceutically active ingredient (col. 31, line 32). It is Examiner's position that some of these powders will coalesce into composite particles as required by Applicant. At a minimum, it would have been obvious to one of ordinary skill in the art who is applying two powder ingredients to apply them together in one particle to ensure that the two ingredients are administered in a desired ratio for treatment of a given medical condition.

14. Claims 63, 77, 80-81, 85, 90, 104, 107-108, 112, 119, 133, 136-137, 141, 148, 151-152, 156 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pletcher *or* Sun in view of Staniforth (WO 92/14451).
Pletcher and Sun teach that which is disclosed above, but fail to teach that their pharmaceutical dosage substrate cores contain an active material.

Staniforth teaches electrostatically powder coating a pharmaceutical dosage form, such as a tablet, which contains an active material (abstract; p. 12, line 14).

Since Pletcher and Sun teach electrostatically coating a drug onto a tablet and Staniforth teaches that tablets containing drugs are electrostatically coated in the art, Staniforth would have reasonably suggested coating active drug core tablets with the method of Pletcher. It would have been obvious to one of ordinary skill in the art to use the teachings of Staniforth in the method of either Pletcher or Sun to electrostatically coat pharmaceutical-containing substrates with the active agents of Pletcher or Sun. Therefore, since many drug therapies include a combination or cocktail of drugs to achieve a desired benefit, it is Examiner's position that it would have been obvious to use a combination of drugs in the method of Pletcher or Sun, i.e., that the substrate of Staniforth contain a different drug than the coating of Pletcher or Sun. It would have been obvious to coat a drug core of Staniforth with a different drug, according to Pletcher or Sun, to achieve such a cocktail.

Sun and Pletcher teach that which is disclosed above, but fail to teach some of the specifics of an electrostatic coating operation.

Staniforth, for example, teaches electrostatic powder coating onto pharmaceutical substrates using corona or triboelectric charging and micron-sized powders, similar to Pletcher and Sun's methods. Specifically Staniforth teaches Applicant's resistivity of the powders and a post-treatment to secure the powders to the substrates. Staniforth teaches that, to maintain the pharmaceutical substrate integrity, using a fusing

temperature of 50-180 degrees Celcius is appropriate (page 2, lines 15-18; page 8, lines 10-15; page 9, lines 13-21; page 10, line 7).

Since Pletcher and Sun and Staniforth teach the use of pharmaceuticals in electrostatic powder coating operations and Staniforth teaches a resistivity and fusing temperatures for such operations, Staniforth would have reasonably suggested the use of his resistivity and fusing temperatures in the method of either Pletcher or Sun. It would have been obvious to one of ordinary skill in the art to use the teachings of Pletcher in the method of either Pletcher or Sun to provide Pletcher or Sun with an adherent film of powder coating material that will not easily wear off prior to use.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
Technology Center 1700
April 19, 2004